DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

[Docket No. 03D–0001]

Draft Guidance for Industry on Nonclinical Safety Evaluation of Pediatric Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Nonclinical Safety Evaluation of Pediatric Drug Products." The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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FOR FURTHER INFORMATION CONTACT: Karen Davis Bruno, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Nonclinical Safety Evaluation of Pediatric Drug Products." Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. In most cases to date, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some drug effects also may be difficult to detect in clinical trial or during routine postmarketing surveillance.

The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It describes how juvenile animal studies can be useful in monitoring, timing, and phasing of trials for initial enrollment in pediatric clinical studies. The draft guidance is intended to serve as a resource for general considerations in animal testing and to provide recommendations based on the available science and pragmatic considerations. The scope of animal studies is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on "Nonclinical Safety Evaluation of Pediatric Drug Products." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Managment Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 1/21/03

January 21, 2003.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

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